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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/931,009	08/17/2001	Theresa H. Smith	US 1257/01 (VA)	2825

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EXAMINER

LIU, SAMUEL W

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/931,009

Applicant(s)

SMITH, THERESA H.

Examiner

Samuel W Liu

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) 10-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☒ Claim(s) 1 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11-28-01</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

Claims 1-15 are pending.

Election/restriction

Applicant's election with traverse of Group I, claims 1-9 in the response filed 16 March 2004 is acknowledged. The traversal is on the ground that claim 10 (Group II) and claim 11 (Group III) depend from claim 7; thus, claims 10-11 should be also examined with the elected Group I. Applicant's argument has been fully considered but it is found to be not persuasive. Group I method is patentably different/distinct from the methods of Group II (claims 7 and 10) and Group III (claims 7 and 11) in that Group I is directed to a method of inducing pro-inflammatory effect in synovial cells whereas (i) Group II is directed to a method of treating or preventing inflammatory of synovial cells (joint) in a subject wherein the analog peptide of claim 7 is required for said method; and (ii) Group III is directed to a method of treating or preventing rheumatoid arthritis in a subject wherein the analog peptide of claim 7 is also required for said method. These methods constitute patentably distinct inventions comprising distinct/different methodologies, starting material, objectives, technical considerations, endpoint or/and treatment outcome (see also the Office action mailed 22 December 2003). The requirement is therefore still deemed proper and is therefore made FINAL.

Claims 10-15 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Therefore, elected claims 1-9 are under examination to the extent that they are drawn to the elected invention.

Art Unit: 1653

Please note that applicant's request (filed 16 March 2004) for extension of time of two months has been entered.

IDS

The references of IDS filed 28 November 2001 have been considered. It is of note however that there are no patent references cited at page 1 of PTO 1449 form of said IDS.

Specification/Claim/ Objections

The disclosure is objected to because of the following informalities:

(1) In page 9, paragraph [0025], line 2, "RA synovial lines" should be changed to "RA synovial cell lines".

(2) In claims 1 and 7, "SEQ ID NO..2" should be changed to "SEQ IDE NO:2".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter that the applicant regards as his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 appears to be incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are culturing the exposed cells and obtaining or/and assessing the result of inducing pro-inflammatory effect in synovial cells. The dependent claims are also rejected.

Art Unit: 1653

Claims 5 and 6 are the composition claims which as written depend from the process claim 1. Such the claim dependency renders the claims indefinite.

Claim 7 is indefinite in “wherein proline 4 comprises an amide form of proline” because the claim does not make it clear as to whether or not said “proline 4” refers to (i) the 4th proline residue out of total proline residues within the claimed peptide that *comprises* SEQ ID NO:2, or (ii) residue 4 of Gly-Pro-Arg-Pro (SEQ ID NO:2), and because “proline 4” *per se cannot comprises* an amide form of proline (i.e., Pro-NH₂); suggest “proline 4 is an amide form of proline”. Additionally, the claim recites “wherein proline 4 comprises...” without setting forth in which peptide said proline 4 resides; such the recitation renders claim 7 indefinite. Suggest “C-terminal proline residue of SEQ ID NO:2 is amidated at carboxyl group of said residue”. The dependent claims are also rejected.

Claim Rejections - 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Stuber, W. *et al.* (US Pat. No. 5478810).

Stuber et al. teach a peptide comprising the SEQ ID NO:2 sequence (i.e., GPRP) of the instant application wherein the 4th proline is amidated (see the patent claim 6, and SEQ ID NO:16, i.e., GPRPPP-NH₂), which anticipates the instant claim 7.

Art Unit: 1653

Stuber et al. teach a medicament (i.e., therapeutic composition) comprising the SEQ ID NO:16 (see abstract), as applied to the instant claim 8.

Also, Stuber et al. teach a derivative of the peptide of SEQ ID NO:16 structure (see the patent claim 6, i.e., GPRPPP-NH(isopropyl)), which anticipates the instant claim 9.

Note that the recitation “the analog being substantially ineffective at inducing expression or production of cell adhesion molecules” is an inherent property of the claimed peptide, and said “inducing expression ...” appears to refer to an intended use for the peptide and there is no patentable weight associated with the use of said peptide because structure and biological activity/property of the peptide will not be altered due to the above-indicated use of said peptide.

In addition, Stuber et al. teach a peptide consisting of the SEQ ID NO:2 sequence (i.e., GPRP) of the instant application wherein the N-terminal proline (i.e., the 4th residue) is amidated, i.e., GPRP-NH₂ (see column 1, lines 57-59). This Stuber et al. teaching thus also anticipates the instant claim 7. Note that this rejection is made because of the ambiguity of the recitation “proline 4” (see the rejection under 35 USC, the second paragraph).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is 571-272-0949. The examiner can normally be reached from 9:00 a.m. to 5:00 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this

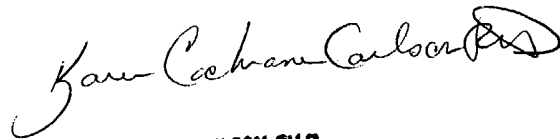
Art Unit: 1653

application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.



Samuel Wei Liu, Ph.D.

April 21, 2004



KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER